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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,566	10/16/2000	Dasa Lipovsek	50036/021004	1736

31020 7590 10/02/2002

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EXAMINER
AUDET, MAURY A

ART UNIT	PAPER NUMBER
1653	13

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE

Office Action Summary	Application No. 09/688,566	Applicant(s) LIPOVSEK ET AL.	
	Examiner Maury A. Audet	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-32, drawn to non-antibody protein, classified in class 530, subclass 300+.

II. Claim 33, drawn to a nucleic acid, classified in class 536, subclass 231.

III. Claim 34, drawn to a method of obtaining a derivative non-antibody protein utilizing a scaffold protein, classified in class 530, subclass 333 and/or 344.

IV. Claim 35, drawn to a method of obtaining a derivative non-antibody protein utilizing a candidate protein, classified in class 530, subclass 333 and/or 344.

V. Claims 36, drawn to a method of obtaining a compound which binds to a non-antibody (candidate protein), classified in class 530, subclass 333 and/or 344.

VI. Claims 37, drawn to a method of detecting a compound in a sample, classified in class 530, subclass 333 and/or 344.

VII. Claim 38-41, 43, drawn to a non-antibody protein that binds tumor necrosis factor-α (TNF-α), wherein said protein comprises any one of SEQ ID NOS: 38-140, classified in class 530, subclass 300.

VIII. Claim 42, drawn to a nucleic acid encoding non-antibody protein that binds tumor necrosis factor-α (TNF-α), classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding same. The DNA molecules have utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Invention I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in antibody production for example.

Invention I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section

806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the recombinant production of protein for example.

Invention I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in the recombinant production of protein for example.

Inventions III, IV, V, and VI are related as process of use for the product of Invention I. Furthermore, Inventions III and IV are related to each other as methods for obtaining of Invention I. However, they differ in that Invention III involves the use of non-antibody scaffold proteins to obtain Invention I, whereas Invention IV involves the use of a candidate protein for obtaining Invention I. In the instant case, both scaffold proteins (Invention III) and candidate proteins (Invention IV) may be used in a materially different process to obtain different, although not always the same, proteins beyond those in Invention I. Invention V is different from both Invention III and IV, because Invention V is directed to obtaining the compound(s) that bind to Invention I, utilizing a candidate protein. Invention VI is different from both Invention III and IV, and Invention V, because Invention V is solely directed to detecting a compound in a sample that binds to Invention I.

The nucleic acids of Invention VIII are related to the protein of Invention VII by virtue of encoding same. The DNA molecules have utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention VII. Although the DNA molecule and protein

are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The amino acid sequences of Invention VI and VIII (SEQ ID NOS: 38-140) are assumed at this stage, to be similar and therefore these 102 sequences have not been separated into individual Inventions. If Applicants elect Invention VII or VIII, it is requested that Applicants set forth a single sequence (or part thereof) that will be used in a sequence search. If any art is found reading upon that sequence, the remaining sequences will be considered as rendered obvious over the prior art.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 4:30 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached at 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist who telephone number is 703-308-1235.

Maury Audet
Examiner
Art Unit 1653

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September 30, 2002

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER